CANCER RESEARCH UK & UCL CANCER TRIALS CENTRE

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8th November 2010

Ms Anna Bradnam
Hertfordshire REC
REC Office
Victoria House
Capital Park
Fulbourn
Cambridge CB21 5XB

Dear Ms Bradnam,

RE: A Phase II Single Arm Study of the use of CODOX-M/IVAC with Rituximab (R-CODOX-M/IVAC) in the treatment of patients with Diffuse Large B-Cell Lymphoma (DLBCL) or Burkitt's Lymphoma (BL) of International Prognostic Index High or High – Intermediate Risk

REC reference number: 05/Q0201/81 EudraCT Number: 2005-003479-19

Sponsor's Protocol number: UCL/05/134

Please find enclosed the following:

RCM - Addendum I to PIS v7.1 01.09.10

RCM - PIS - v7.2 - 05.11.10 (tracked & untracked)

The current version of the PIS (v7.1 dated 01.09.10) states that the total number of CT scans in the trial is 2 instead of 4 as stated in the protocol and treatment schedule. This has now been amended in the updated version 7.2, dated 05.11.10. Only one patient has been consented to the information given in version 7.1, and will be re-consented.

Please do not hesitate to contact me should you have any further queries.

Yours sincerely,

Toyin Adedayo

Clinical Trials Coordinator

Cc: MHRA

